510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k042191

B. Purpose for Submission:
New Device

C. Analyte:
Potassium

D. Type of Test:
Quantitative

E. Applicant:
Diazyme Laboratories

F. Proprietary and Established Names:
Diazyme Potassium Enzymatic Assay Kit
Diazyme Enzymatic Potassium Serum Controls

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1600 Potassium Test System
   21 CFR 862.1660 Quality Controls

2. Classification:
   Class II - 21 CFR 862.1600 Potassium Test System
   Class I (reserved) - 21 CFR 862.1660 Quality Controls

3. Product Code:
   Diazyme Potassium Enzymatic Assay Kit and Calibrators- MZV, JIT
   Diazyme Enzymatic Potassium Serum Controls- JJX

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   Diazyme Potassium Enzymatic Assay Kit in conjunction with Diazyme Potassium Low and High Calibrators, are intended for the quantitative determination of sodium (K) in serum.

Diazyme Potassium Enzymatic Assay Kit contains a low level standard and a high level standard. The standards are used to generate a linear graph that will be used in the calculation of potassium concentrations in unknown serum samples.
Diazyme Potassium Enzymatic Assay has controls for normal serum potassium level and abnormal serum potassium level. The controls are used as reference samples for checking the functionality of the Diazyme Potassium Enzymatic Assay.

2. Indication(s) for use:
Diazyme Potassium Enzymatic Assay Kit in conjunction with Diazyme Potassium Low and High Calibrators, are intended for the quantitative determination of sodium (K) in serum.
Diazyme Potassium Enzymatic Assay Kit contains a low level standard and a high level standard. The standards are used to generate a linear graph that will be used in the calculation of potassium concentrations in unknown serum samples.
Diazyme Potassium Enzymatic Assay has controls for normal serum potassium level and abnormal serum potassium level. The controls are used as reference samples for checking the functionality of the Diazyme Potassium Enzymatic Assay.

3. Special condition for use statement(s):
For Prescription Use Only

4. Special instrument Requirements:
This assay can be performed manually or in an automated chemistry analyzer capable of maintaining 37 ºC and reading absorbance at 450 nm.

I. Device Description:

The Diazyme Potassium Enzymatic Assay is a spectrophotometric assay intended for the quantitative determination of potassium ions in human serum. The assay includes high and low calibrators. The assay controls are sold separately. The Diazyme Potassium Enzymatic Assay consists of 4 components that are used in 2 stages (diluent 1 and enzyme 1 forms reagent 1 and diluent 2 and substrate 2 forms reagent 2). Reagent 1 is mixed with a serum sample and incubated at 37 °C and followed by reagent 2. The absorbance is read at 450 nm after 3 minutes and then again after 2 additional minutes.
The Diazyme Potassium Enzyme Calibrator set is a bi-level serum calibrator with high (7 mM) and low (3 mM) potassium levels. The calibrator is prepared with Tris, pH 7.5 and potassium chloride equivalent to the high or low level calibrator.
The Diazyme Enzymatic Potassium Serum Control kit is sold as a lyophilized bi-level serum control with normal (4.4 mM) and abnormal (6.4 mM) potassium levels. The controls are pooled sodium free human sera that were tested and found negative for HIV, HBV and HCV using FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Sychron LX I 725 Clinical System

2. Predicate K number(s):
   k023049

3. Comparison with predicate:

Diazyme Potassium Enzyme Assay Kit

Similarities		
Item	**Device**	**Predicate**
Indications for Use	Diazyme Potassium Enzymatic Assay Kit is for quantitative *in vitro* determination of Potassium in human serum.	Synchron LX Systems is used for quantitative *in vitro* determination of Potassium in human serum, plasma and urine
Sample	Serum	Serum, Plasma and Urine
Analyte	Potassium	Potassium
Differences		
Item	**Device**	**Predicate**
Test Principle	Potassium is determined enzymatically via potassium dependent urea amidolyase activity with 1-methoxy-5-methyl-phenazinium methyl sulfate (PMS) as a substrate. After a series of reactions, the absorbance at 450 nm of the product Formazan is proportional to the potassium concentration.	Potassium is determined through a microprocessor-based instrument using ion-selective electrodes.
Assay Range	2- 8 mmol/L	1- 15 mmol/L

Diazyme Enzymatic Potassium Serum Controls

Similarities		
Item	**Device**	**Predicate**
Indications for Use	Diazyme Potassium Enzymatic Assay has controls for normal serum Potassium level and abnormal serum Potassium level. The controls are used as reference samples for checking the functionality of the Diazyme Potassium Enzymatic Assay.	Synchron LX Systems is has controls for 2 serum Potassium levels. The Controls are used as a reference for checking the functionality of the Synchron LX System.
Analyte	Potassium	Potassium

K. Standard/Guidance Document Referenced (if applicable):

None Referenced

L. Test Principle:

Potassium is determined enzymatically via potassium dependent urea amidolyase activity with 1-methoxy-5-methyl-phenazinium methyl sulfate (PMS) as a substrate. After a series of reactions, the absorbance at 450 nm of the product Formazan is proportional to the potassium concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Two levels of potassium specimens, 4.4 mM and 6.4 mM, were tested within run 80 times time in 4 replicates over 20 days to obtain a CV of 3.2% and 3.0% respectively. The same levels were tested for precision to obtain a CV of 5.3% and 3.3% respectively.
The Diazyme Enzymatic Potassium Serum Controls were tested for reproducibility at two laboratories with the Hitachi 917 on serum control samples containing 3.9 mM (low) and 6.1 mM (high) potassium. Site 1 obtained with an average of 3.9 mM and 6.1mM potassium for the low and high controls respectively. Site 2 obtained an average of 4.0 mM and 6.2 mM potassium for the low and high controls respectively.

b. Linearity/assay reportable range:

Linearity was tested on serum samples spiked with potassium that ranged from 2 mM to 10 mM. Samples were diluted with distilled water or potassium chloride to achieve targeted concentrations. The linearity equation was $Y= 0.0777x + 0.3784$ with a R^2 of .9952 using the Cobas Mira.

c. *Traceability (controls, calibrators, or method):*
The Diazyme Potassium controls are sold separately and are prepared with pooled human sera that were tested for HIV, HBV and HCV using FDA approved methods.
The Diazyme Potassium calibrators are included with the Diazyme Potassium Assay and are prepared gravimetrically using commercially available solutions.
Both a real time and an accelerated stability study were conducted for the Diazyme Enzymatic Potassium Assay kit and they supported a stability of 8 months at 2-8 °C for the lyophilized form and 14 days at 2-8 °C for the reconstituted form.
The Diazyme Potassium Enzymatic Calibrators were studied in real time at 4 °C and the results supported a stability of 6 months at 4 °C. There is an ongoing real time study.
The Diazyme Potassium Serum Controls were studied using an accelerated rate equation and a shelf life of 3 months at 2-8 °C in the lyophilized form and 14 days at 2-8 °C.

d. *Detection limit:*
See Linearity Above

e. *Analytical specificity:*
Interference was tested on cations and substances normally present in serum with the Diazyme Enzymatic Potassium Assay by spiking 4.4 mM potassium serum samples. The study found less than 10% deviation when tested at the following levels and substances:
1 mM NH_4Cl, 1.5 mM NaPi, 5 mM $CaCl_2$, 200 mM NaCl, 0.25 mM $CuCl_2$, 0.25 $ZnCl_2$, 0.025 mM $FeCl_3$, 5 mM Ascorbic Acid, 5 mM Glucose, 10 mg/ dL Bilirubin and 500 mg/dL Triglyceride.

f. *Assay cut-off:*
See Linearity Above.

2. Comparison studies:
   a. *Method comparison with predicate device:*
   Thirty four serum samples, 26 diluted samples and eight calibrators and/or controls were tested with both the Diazyme Enzymatic Potassium Assay and the Synchron LX I 725 Clinical System. An equation of $Y = 1.001X + 0.18$ was obtained with an R^2 of .9665.

   b. *Matrix comparison:*
   Not applicable

3. Clinical studies:
   a. *Clinical sensitivity:*
   Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data (when a and b are not applicable):
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
A normal potassium serum values range from 3.5 to 5.5 mM (13.7- 19.9 mg/dL) was provided as obtained from the literature.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.